AMENDMENTS 001-027
by the Committee on Employment and Social Affairs

Report
Laura Agea A8-0382/2018
Protection of workers from the risks related to exposure to carcinogens or mutagens at work


Amendment 1

Proposal for a directive
Recital 1

Text proposed by the Commission

(1) Principle 10 of the European Pillar of Social Rights, proclaimed at Gothenburg on 17 November 2017, provides that every worker has the right to healthy, safe and well-adapted work environment. The right to a high level of protection of the health and safety at work, as well as to a working environment adapted to the professional needs of workers and which enables them to prolong their participation in the labour market includes also protection from carcinogens and mutagens at the workplace.

Amendment

(1) Delivering on the principles and rights provided for by the European Pillar of Social Rights, proclaimed at Gothenburg on 17 November 2017 is a shared political commitment and responsibility of the Union, the Member States and the social partners, in accordance with their respective competences. Principle 10 of the European Pillar of Social Rights provides that every worker has the right to healthy, safe and well-adapted work environment. The right to a high level of protection of the health and safety at work, as well as to a working environment adapted to the professional needs of workers also includes protection from carcinogens and mutagens at the workplace, irrespective of the arrangements for or duration of the employment or the exposure.
Amendment 2
Proposal for a directive
Recital 1 a (new)

Text proposed by the Commission

Article 153 TFEU establishes a framework for the social partners to negotiate and enforce agreements relating to occupational health and safety and the Charter of Fundamental Rights of the European Union guarantees, in particular, the fundamental right to life (Article 2), and the right to fair and just working conditions with respect to health, safety and dignity (Article 31(1)).

Amendment 3
Proposal for a directive
Recital 2

Text proposed by the Commission

(2) Directive 2004/37/EC of the European Parliament and of the Council aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A consistent level of protection from the risks related to carcinogens and mutagens is provided for in Directive 2004/37/EC by a framework of general principles to enable Member States to ensure the consistent application of the minimum requirements. Binding occupational exposure limit values established on the basis of available information, including scientific and
technical data, economic feasibility, a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace, are important components of the general arrangements for the protection of workers established by Directive 2004/37/EC. The minimum requirements provided for in Directive 2004/37/EC aim to protect workers at Union level. More stringent binding occupational exposure limit values can be set by Member States.

Amendment 4
Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission

(2a) Directive 2004/37/EC aims to cover substances or mixtures which meet the criteria for classification as a category 1A or 1B carcinogen and/or mutagen set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council as well as substances, mixtures or processes referred to in Annex I to this Directive. The substances which meet the criteria for classification as a category 1A or 1B carcinogen or mutagen set out in Annex I to Regulation (EC) No 1272/2008 are those with a harmonised classification or classified in accordance with Article 4 or 36 thereof and notified to the European Chemicals Agency (ECHA) pursuant to article 40 thereof. Those substances are listed in the public Classification and Labelling Inventory maintained by ECHA. Further
cooperation with IARC should be sought so that in future substances classified by IARC as carcinogens category 1 or 2A are also deemed to meet the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008.

Amendment 5
Proposal for a directive
Recital 2 b (new)

Text proposed by the Commission

(2b) Wide differences in the Member States regarding the setting of limit values for the carcinogens and mutagens persist, which leads to differing levels in the protection of workers across the Union and also distorts competition.

Amendment 6
Proposal for a directive
Recital 3

Text proposed by the Commission

(3) Occupational exposure limit values are part of risk management under Directive 2004/37/EC. Compliance with those limit values is without prejudice to other obligations of employers pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers’ exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen or mutagen by a substance, mixture or process which is not dangerous or is less dangerous to workers’ health, the use of a closed system or other measures aiming to reduce the

Amendment

(3) Occupational exposure limit values are part of risk management under Directive 2004/37/EC. The limit values should be revised regularly in accordance with the precautionary principle and the principle of the protection of workers, and in light of sound available scientific and technical data concerning carcinogens and mutagens. The limit values for substances listed in Annex III aim to minimise, to the extent possible, the additional risk of cancer arising from working with those substances. On that basis the additional risk is not expected to be more than 1 in 2500 of the time-weighted average of a standard working life. Consideration should also be given to improving measurement techniques, risk
In that context, it is essential to take the precautionary principle into account where there are uncertainties.

Amendment 7
Proposal for a directive
Recital 3 a (new)

Text proposed by the Commission

(3a) In pharmacology, hazardous drugs are drugs that are known to cause harm, because of their genotoxicity, carcinogenicity, teratogenicity, reprotoxicity and other forms of toxicity at low doses\(^a\). Those drugs include cytotoxic agents, which inhibit or prevent the rapid growth and division of cancer cells, and are primarily used to treat cancer, frequently as part of a chemotherapy regime. However, the cytotoxic drugs available for current use are generally non-selective and are therefore likely to damage normal (non-tumour) cells too. Thus, many cytotoxic drugs are known to be genotoxic, carcinogenetic or mutagenic.

\(^a\) IARC monographs on the evaluation of carcinogenic risks to humans, volumes 1-121
http://monographs.iarc.fr/ENG/Classifica
Amendment 8

Proposal for a directive
Recital 3 b (new)

Text proposed by the Commission

(3b) It is therefore important to protect workers exposed to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of hazardous drugs, including cytotoxic drugs, and work involving exposure to carcinogenic or mutagenic substances in the context of providing services relating to cleaning, transport, laundry, waste disposal of hazardous drugs or of materials contaminated by hazardous drugs, and personal care for patients treated with hazardous drugs. As a first step, the Commission has issued dedicated guidance to reduce occupational health and safety risks in the healthcare sector, including on the risks related to exposure to cytotoxic drugs, in a dedicated guide to prevention and good practices.

Amendment 9

Proposal for a directive
Recital 3 c (new)

Text proposed by the Commission

(3c) As a second step, the Commission should, taking into account the latest developments in scientific knowledge, assess the possibility of extending the scope of Directive 2004/73/EC to include hazardous drugs, including cytotoxic drugs, which are carcinogenic or mutagenic, or to propose a more appropriate legal instrument, in order to ensure the occupational safety of workers handling those drugs. Accordingly, the
Commission should present, if appropriate, and after consulting the social partners, an appropriate legislative proposal. In doing so, it is imperative, however, that, in accordance with Article 168(1) TFEU, access to the best available treatments for patients should not be questioned or jeopardised.

Amendment 10
Proposal for a directive
Recital 5

Text proposed by the Commission

(5) Maximum levels for the exposure of workers to some carcinogens or mutagens are established by values which, pursuant to Directive 2004/37/EC, must not be exceeded.

Amendment

(5) Maximum levels for the exposure of workers to some carcinogens or mutagens are established in Annex III by values which, pursuant to Directive 2004/37/EC, must not be exceeded. Practical recommendations for the health surveillance of workers may be laid down in Annex II to Directive 2004/37/EC but are not made mandatory.

Amendment 11
Proposal for a directive
Recital 6

Text proposed by the Commission

(6) This Directive strengthens the protection of workers’ health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC in the light of available information, including new scientific and technical data and evidence-based best practices, techniques and protocols for exposure level measurement at the workplace. That information should, if possible, include data on residual risks to the health of

Amendment

(6) This Directive strengthens the protection of workers’ health and safety at their workplace. The Commission should review this Directive on a regular basis and make legislative proposals if appropriate. New limit values should be set out in Directive 2004/37/EC in the light of available information, including new scientific and technical data and evidence-based best practices, techniques and protocols for exposure level measurement
workers, recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL) and opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH). Information related to residual risk, made publicly available at Union level, is valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens. Transparency of such information should be further encouraged. 

at the workplace. That information should, if possible, include data on residual risks to the health of workers, recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL) and opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH) and monographs of the International Agency for Research on Cancer (IARC\(^1\)). Information related to residual risk is valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens, and should be made publicly available at Union level. Transparency is a tool for prevention in this context and should be ensured. This Directive follows the specific recommendations of SCOEL and the ACSH, the importance of which has been highlighted in previous amendments to Directive 2004/37/EC.

\(^1\) The International Agency for Research on Cancer was set up in 1965 by the United Nations World Health Organization.

Amendment 12

Proposal for a directive
Recital 7

Text proposed by the Commission

(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection. Amendments to Annex III to Directive 2004/37/EC provided for in this Directive constitute a further step in a longer term process initiated to update Directive 2004/37/EC.

Amendment

(7) It is also necessary, in light of scientific data, to consider other absorption pathways than inhalation of all carcinogens and mutagens, in view of observations regarding the possibility of uptake through the skin - concretely through skin notation, in order to ensure the best possible level of protection. Amendments to Annex III to Directive 2004/37/EC provided for in this Directive constitute a further step in a longer term process.
Amendment 13
Proposal for a directive
Recital 10 a (new)

\textit{Text proposed by the Commission}

(10a) The 2018-2019 campaign the European Agency for Safety and Health at Work (EU-OSHA) on Healthy Workplaces: Manage Dangerous Substances is a first step. EU-OSHA needs to work closely with Member States and reinforce the exchange of good practices, to provide tailored information and examples of good practices to workers in contact with certain substances, in particular cytotoxic, highlighting policy developments and the legislative framework already in place.

Amendment 14
Proposal for a directive
Recital 11 a (new)

\textit{Text proposed by the Commission}

(11a) Cadmium (Cd) is a naturally occurring element to which humans are exposed from cigarettes, food and industrial sources. Kidneys, and possibly bones, are the most sensitive target of systemic Cd toxicity following occupational exposure (critical target organs). Cd is a cumulative toxicant; the systemic manifestations associated with chronic exposure are related to the body burden of the element (liver and kidney content). Biological markers such as Cd-U (cadmium excretion in urine) allow the assessment of body burden, and the integration of all sources of Cd exposure, including by means of contaminated food and smoking. The use of such biomarkers
in most epidemiological studies conducted in occupational settings has allowed researchers to document reliable dose-effect-response relationships. A biological limit-value would thus protect workers against systemic toxicity of Cd, mainly renal and bone effects. Biological monitoring can thus contribute to the protection of workers at the workplace by but only as a means of complementing the monitoring of the concentration for cadmium (and its inorganic compounds) in the air within the breathing zone of a worker.

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https://circabc.europa.eu/sd/a/13cad802-1f3c-40c0-bce4-6838cf5fcf4ff/OPIN-336%20Cadmium%20and%20its%20inorganic%20compounds.pdf

Amendment 15
Proposal for a directive
Recital 12

Text proposed by the Commission

(12) With regard to cadmium, a limit value of 0,001 mg/m$^3$ may be difficult to be complied with in some sectors in the short term. A transitional period of seven years should therefore be introduced during which the limit value 0,004 mg/m$^3$ should apply.

Amendment

(12) With regard to cadmium, a limit value of 0,001 mg/m$^3$ may be difficult to be complied with in some sectors in the short term. A transitional period of seven years should therefore be introduced during which the limit value 0,004 mg/m$^3$ should apply. In Member States which implement biological monitoring, the biological limit value should be 2μg Cd/g creatinine and the 8-hour TWA limit value should be 0,004 mg/m$^3$ (respirable fraction). The introduction of that limit-value does not require a transitional period. The Commission should draw up guidelines for the practical implementation of such biological monitoring.
Amendment 16
Proposal for a directive
Recital 17

Text proposed by the Commission

(17) Formaldehyde meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is a local acting genotoxic carcinogen. It is possible, on the basis of the available information, including scientific and technical data, to set a long and short term limit value for that carcinogen. Formaldehyde is also a contact allergen to the skin (skin sensitiser). It is therefore appropriate to establish a limit value for formaldehyde and to assign a notation for skin sensitisation. In addition, upon request of the Commission, ECHA is also gathering existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses.

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Amendment

(17) Formaldehyde meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is a local acting genotoxic carcinogen. There is sufficient evidence in humans for the carcinogenicity of formaldehyde. Formaldehyde causes cancer of the nasopharynx and leukaemia. On the basis of the available information, including scientific and technical data, it is possible to set a long and short term limit value for that carcinogen. Formaldehyde is also a contact allergen to the skin (skin sensitiser). It is therefore appropriate to establish a limit value for formaldehyde and to assign a notation for skin sensitisation. In addition, upon request of the Commission, ECHA is also gathering existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses.

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Amendment 17
Proposal for a directive
Recitals 17 a (new)

Text proposed by the Commission

(17a) Formaldehyde fixatives are routinely used in Union healthcare centres for the standardised fixation of tissue sample given their convenience in handling, high degree of accuracy and extreme adaptability, which have, to date, not been reached by any other group of fixative. As a result, a pathologist’s diagnosis of a variety of diseases, including cancer, is based on the recognition of microscopic traces in tissue fixed in a formaldehyde fixative. The concentrations of formaldehyde used in healthcare are minimal in comparison with those used in industry and, while healthcare centres in the Union should take all appropriate measures to keep formaldehyde exposure among their staff within safe limits, the healthcare sector is likely to have no difficulty in respecting the limit-value set in this Directive.

Amendment 18

Proposal for a directive
Recitals 17 b (new)

Text proposed by the Commission

(17b) In some Member States formaldehyde is routinely used for the purposes of embalming deceased persons as part of their cultural or religious practices. The funeral sector is likely to find a limit value of 0,3ppm to be difficult to comply with without significant short-term effects on capacity. A transitional period of three years should therefore be introduced for the sector during which the limit-value of 0,5ppm should apply.
Amendment 19
Proposal for a directive
Recital 18

Text proposed by the Commission

(18) 4,4’-Methylene-bis(2-chloroaniline)(MOCA) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. The possibility of a significant uptake through the skin was identified for MOCA. It is therefore appropriate to establish a limit value for MOCA and to assign to it a skin notation. In addition, it was identified as a substance of very high concern (SVHC) pursuant to Article 57(a) of Regulation EC No 1907/2006 and included in Annex XIV to that Regulation, requiring authorisation before it can be placed on market or used. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for MOCA.

Amendment

(18) 4,4’-Methylene-bis(2-chloroaniline)(MOCA) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. Its carcinogenicity, together with its manifest genotoxic characteristics, has made it possible to classify that substance as carcinogenic to humans. The possibility of a significant uptake through the skin was identified for MOCA. It is therefore appropriate to establish a limit value for MOCA and to assign to it a skin notation. In addition, it was identified as a substance of very high concern (SVHC) pursuant to Article 57(a) of Regulation EC No 1907/2006 and included in Annex XIV to that Regulation, requiring authorisation before it can be placed on market or used. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for MOCA.

Amendment 20
Proposal for a directive
Recital 21

Text proposed by the Commission

(21) The limit values set out in this Directive are to be kept under review to ensure consistency with Regulation (EC) No 1907/2006 of the European Parliament and of the Council\(^{50}\), in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and derived no effect levels for hazardous chemicals under that Regulation in order to

Amendment

(21) The limit values set out in this Directive are to be kept under \textit{permanent scrutiny and regular} review to ensure consistency with Regulation (EC) No 1907/2006 of the European Parliament and of the Council\(^{50}\), in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and derived no effect levels for hazardous chemicals under that Regulation in order to
protect workers effectively.

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Amendment 21

Proposal for a directive
Recital 23

Text proposed by the Commission

(23) In implementing this Directive Member States should avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings. Member States are therefore invited to assess the impact of their transposition act on SMEs in order to make sure that SMEs are not disproportionately affected, with specific attention for micro-enterprises and for administrative burden, and to publish the results of such assessments.

Amendment

(23) In implementing this Directive Member States should take into account that SMEs and microenterprises, which represent a large majority of enterprises in the Union, have limited financial, technical and human resources. Member States are therefore invited to assess the impact of their transposition act on SMEs in order to make sure that SMEs are not disproportionately affected, with specific attention for micro-enterprises and for administrative burden, and to publish the results of such assessments, while maintaining levels of equal protection for all workers, compliance of SMEs and microenterprises should be facilitated. Against that background, specific measures such as incentives and digital tools could help SMEs and microenterprises better to comply with the obligations laid down in Directive 2004/37/EC and move towards the elimination of carcinogenic or mutagenic risks. The social partners should
In Article 14, paragraph 1 is replaced by the following:

“In Article 14, paragraph 1 is replaced by the following:

1. The Member States shall establish, in accordance with national law or practice, arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment referred to in Article 3(2) reveal a risk to health or safety. The doctor or authority responsible for the health surveillance of workers may indicate that health surveillance must continue after the end of exposure for as long as they consider it to be necessary to safeguard the health of the worker concerned.

1a. Where Member States choose to implement biological monitoring, the limit values set out in Part B of Annex III shall apply.”
Amendment 24

Proposal for a directive
Article 1 – paragraph -1 b (new)
Directive 2004/37/EC
Article 18 b (new)

Text proposed by the Commission

The following article is inserted after Article 18a:

“Article 18b
By the fourth quarter of 2019, the Commission shall, on the basis of scientific data and appropriate consultation, assess the possibility to amending the scope of this Directive to include a list of hazardous drugs, including cytotoxic drugs, which are carcinogenic or mutagenic, or to propose a more appropriate legal instrument in order to ensure occupational safety of workers handling such drugs. On that basis, the Commission shall present, if appropriate, and after consulting management and labour, a legislative proposal.”

Amendment 25

Proposal for a directive
Article 1 – paragraph-1 c (new)
Directive 2004/37/EC
Annex II – point 2 a (new)

Text proposed by the Commission

In Annex II, the following point is inserted:

“2a. Where biological monitoring is carried out, such monitoring should take into consideration biological values recommended by SCOEL as well as other available guidance and information at Union and national level.”
**Amendment 26**

*Proposal for a directive
Annex
Directive 2004/37/EC
Annex III – Part A – table – row 4*

*Text proposed by the Commission*

| Formaldehyde | 0,37 | 0,3 | 0,7 | 0,6 | Dermal sensitisation (9) |

**Amendment**

| Formaldehyde | 0,37 | 0,3 | 0,7 | 0,6 | Dermal sensitisation (9) | **Limit value 0,5 ppm for the funeral and embalming sectors until xx yyyy 202z [3 years]** |

**Amendment 27**

*Proposal for a directive
Annex
Directive 2004/37/EC
Annex III – point B*

*Text proposed by the Commission*

**Amendment**

*B. OTHER DIRECTLY RELATED PROVISIONS*

p.m.

*Point B of Annex III is replaced by the following:*

“In Member States which implement biomonitoring for cadmium exposure as set out in Article 14(1) and point 2a of Annex II, such monitoring shall include the measurement of the urine level of cadmium (CdU) using absorption spectrometry or a method giving...*
equivalent results. The biological limit value shall be 2μg Cd/g creatinine and the 8-hour TWA limit-value shall be 0.004 mg/m³ (respirable fraction). In that case, no transitional period shall be required."